

10/540521

JC17 Rec'd PCT/PTO 24 JUN 2005

PATENT

Customer No. 22,852

Attorney Docket No. 08140.0006

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:	)	
	)	
Hirotaoka HARO	)	Group Art Unit: To Be Assigned
	)	
Application No.: To Be Assigned	)	Examiner: To Be Assigned
	)	
Filed: Concurrently Herewith	)	
	)	
For: A METHOD OF THERAPY FOR	)	
DEGENERATIVE	)	
INTERVERTEBRAL DISCS	)	

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)**

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicant brings to the attention of the Examiner the documents on the attached listing. This Information Disclosure Statement is being filed within three months of the date of entry of the national stage in an international application.

Copies of the listed documents are attached.

Applicant respectfully requests that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the

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documents as prior art against any claim in the application and Applicant determines that the cited documents do not constitute "prior art" under United States law, Applicant reserves the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: June 24, 2005

By: Amy E. Purcell  
Amy E. Purcell  
Reg. No. 53,492

IDS Form PTO/SB/08: Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	To Be Assigned
				Filing Date	June 24, 2005
				First Named Inventor	Hirohiko HARO
				Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	1	of	2	Attorney Docket Number	08140.0006

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS					
Examiner Initials	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

**Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.**

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation <sup>6</sup>
/PEZ/		EP 1 111 047 A2	06/27/2001	YOSHIMURA et al.		
↓		JP 11169176	06/29/1999	MATSUMOTO et al.		English Abstract
		JP 10099084	04/21/1998	YOSHIMURA et al.		English Abstract
		WO 97/40157	10/30/1997	YOSHIMURA et al.		
		WO 90/13561	11/15/1990	BARRETT et al.		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation <sup>6</sup>
/PEZ/		AVAKYAN, "Effect of the Proteolytic Enzymes Trypsin and Chymopain on an Intervertebral Disk Under Experimental Conditions," <i>Chem. Abstr.</i> 78:23, Abstract No. 106601b (1973).	
↓		BENOIST et al., "Chemonucleolysis in the Treatment of Sciatica from Herniated Lumbar Disc," <i>La Nouvelle Presse Médicale</i> 11(28):2121-2124 (1982).	English Abstract
		BUTTLE, "Chemonucleolysis: An Example of Therapeutic Tissue Damage," <i>Research Monographs in Cell and Tissue Physiology</i> 15:269-278 (1988).	
		EINARSON et al., "Chymopain," <i>Drug Intelligence and Clinical Pharmacy</i> 18:560-568 (1984).	
		HARO et al., "The Role of MMP in Intervertebral Disc Tissues—From Disc Degeneration to Herniated Disc," <i>Rheumatism</i> 41(1):44-50 (2001).	No
		HARO et al., "The Role of MMPs in the Resorption Process of Herniated Disc," <i>Connective Tissue</i> 33:51-57 (2001).	English Abstract
		HARO et al., "Matrix Metalloproteinase-3—Dependent Generation of a Macrophage Chemoattractant in a Model of Herniated Disc Resorption," <i>The Journal of Clinical Investigation</i> 105(2): 133-141 (2000).	
		HARO et al., "Matrix Metalloproteinase-7—Dependent Release of Tumor Necrosis Factor- $\alpha$ in a Model of Herniated Disc Resorption," <i>The Journal of Clinical Investigation</i> 105(2):143-150 (2000).	
		HARO et al., "Up-Regulated Expression of Matrilysin and Neutrophil Collagenase in Human Herniated Discs," <i>Journal of Spinal Disorders</i> 12(3):245-249 (1999).	
		HARO et al., "Chemonucleolysis With Human Stromelysin-1," <i>Spine</i> 22(10):1098-1104 (1997).	
		HARO et al., "Upregulated Expression of Chemokines in Herniated Nucleus Pulposus Resorption," <i>Spine</i> 21(14):1647-1652 (1996).	
		HERRON et al., "Does the MMPI Predict Chemonucleolysis Outcome?" <i>Spine</i> 13(1):84-88 (1988).	
↓		KUDO et al., "Experimental Chemonucleolysis with Chymopain in Canine Intervertebral Disks," <i>J. Vet. Med. Sci.</i> 55(2):211-215 (1993).	
		ROBERTS et al., "Matrix Metalloproteinases and Aggrecanase: Their Role in Disorders of the Human Intervertebral Disc," <i>Spine</i> 25(23):3005-3013 (2000).	

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				First Named Inventor	Hirofaka HARO
				Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	2	of	2	Attorney Docket Number	08140.0006

/PEZ/		SAGONA et al., "Pretreatment Serum Levels of IgE to Chymopapain in Reactive Patients," <i>Annals of Allergy</i> 55:674-677 (1985).	
↓		TROISIER et al., "The Treatment of Lumbosciatica by Intra-discal Injection of Proteolytic Enzymes (Nucleolysis)," <i>La Nouvelle Presse Médicale</i> , 9(4):227-230 (1980).	English Abstract
		International Search Report for PCT/JP2003/016580, May 11, 2004.	

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Examiner Signature	/Paul Zarek/	Date Considered	06/24/2008
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.